



Mail Stop PATENT
Attorney Docket No. 24259

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

SHINITZKY et al.

Serial No.: 09/555,964

Examiner: P. Huynh

Filing Date: September 8, 2000

Art Unit: 1644

For: SKIN TEST FOR SCHIZOPHRENIA

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Meir Shinitzky, of Derech Haganim Street 20, 46910 Kfar Shmarvahu, State of Israel, hereby declare that:

I am a co-inventor named in U.S. Patent Application Serial No. 09/555,964, filed September 8, 2000.

I am informed that the pending claims of said application have been rejected as unpatentable over the WO 97/13152 publication in view of Kessler, et al. (Dementia 6(6):330-3), U.S. Patent No. 5,429,947, Burbaea, et al. (ZH Nevropatol Psikhiatr IM S Korsakova 86(1): 103-105) and Jankovic, et al. (J Immunol 135(2 suppl): 583s-587s).

I declare that the WO 97/13152 publication describes my own work, completed in collaboration with Dr. Michael Deckmann, who

is also my co-inventor for the present inventive subject matter. As such, I am thoroughly familiar with the subject matter of WO 97/13152. The 75 kD platelet-protein and the related platelet associated antibodies, which we disclosed in WO 97/13152 to be associated with multi-infarct dementia and dementia of the Alzheimer type, are not the same as the isolated platelet-proteins or fractions thereof having a pI above about 6.5, which we have claimed in the present application.

I further declare that the Kessler, et al. publication, published in Dementia 6(6):330-3, describes my own work, completed in collaboration with Dr. Abraham Kessler and Dr. Bezalel Kessler. As such, I am thoroughly familiar with the subject matter of the Dementia publication. Our Dementia publication demonstrates a statistical correlation between the mean number of platelet dense granules and the incidence of schizophrenia in our experimental group, as well an inverse relationship between the mean number of platelet dense granules and the incidence of dementia. Contrary to the Examiner's conclusions in the Office Action, it is my opinion that the 1995 Dementia publication teaches away from any correlation between the number of platelet dense granules in schizophrenic patients and in Alzheimer-type demented patients.

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As part of the work for the 1995 Dementia publication, we did not isolate a platelet-protein or fraction thereof having a pI above about 6.5, we did not inject anyone with a platelet-protein, and we did not examine anyone for the presence or absence of a DTH reaction to anything. Thus, it is my opinion that, at the time of the Dementia publication in 1995, it was not obvious to one of ordinary skill in the art to use an isolated platelet-protein or fraction thereof having a pI above about 6.5 in a delayed-type hypersensitivity ("DTH") reaction assay, in a method of diagnosing the likelihood of an individual being schizophrenic.

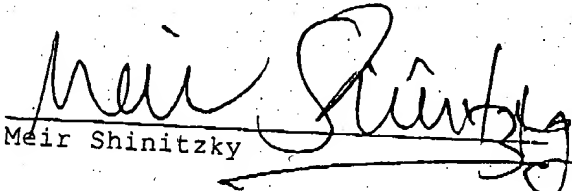
I further declare that I am familiar with the Burbaea, et al. publication, ZH Nevropatol Psikhiatr IM S Korsakova 86(1): 103-105, and know its contents. The Burbaea, et al. publication relates to the isolation of two new proteins from the brain tissues of deceased individuals by the principal investigator, Professor Yankovich, under whose direction Dr. Burbaea worked. In reviewing the data developed by Professor Yankovich and his co-workers, it is apparent that they showed IgG and IgM autoantibody activity, but no T cell involvement. Further, it is apparent that the observed hypersensitivity reaction was light mediated. Thus, despite the characterization by Burbaea

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of the observed reaction as a DTH reaction, the lack of T cell involvement and the light mediated character of the reaction make it clear to one of ordinary skill in the art that Yankovich observed an immediate-type hypersensitivity reaction, not a DTH reaction.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: December 24, 2003


Meir Shinitzky